IN THE CIRCUIT COURT OF CALVERT COUNTY, MARYLAND

ANNA LAUGHLIN
P.O. Box 1711
456 Buffalo Road
Lusby, Maryland 20657

Plaintiff,

v.

Case No.: C14-423

BRETT SHOOP
9114 Philadelphia Road
Suite 100
Baltimore, Maryland 21237

and

MID ATLANTIC MEDICAL, LLC
d/b/a BIOMET MID-ATLANTIC
9114 Philadelphia Road
Suite 100
Baltimore, Maryland 21237
Serve: LSBA, Inc.
c/o Miles & Stockbridge, P.C.
100 Light Street
Baltimore, Maryland 21202

and

BIOMET, INC.
56 East Bell Drive
Warsaw, Indiana 46581
Serve: Corporate Creations Network, Inc.
105 East Jefferson Boulevard, #800
South Bend, Indiana 46601

and

BIOMET ORTHOPEDICS, LLC
56 East Bell Drive
Warsaw, Indiana 46581
Serve: Corporate Creations Network, Inc.
105 East Jefferson Boulevard, #800
South Bend, Indiana 46601

and

EXHIBIT 1

BIOMET U.S. RECONSTRUCTION, LLC)
56 East Bell Drive)
Warsaw, Indiana 46581)
Serve: Corporate Creations Network, Inc.)
105 East Jefferson Boulevard, #800)
South Bend, Indiana 46601)
)
and)
)
BIOMET MANUFACTURING, INC.)
56 East Bell Drive)
Warsaw, Indiana 46581)
Serve: Corporate Creations Network, Inc.)
105 East Jefferson Boulevard, #800)
South Bend, Indiana 46601)
)
Defendants.)
)

COMPLAINT

Plaintiff ANNA LAUGHLIN, for her Complaint against Defendants BRETT SHOOP ("SHOOP"), MID ATLANTIC MEDICAL, LLC d/b/a BIOMET MID-ATLANTIC (MAM), BIOMET, INC., ("BMI"), BIOMET ORTHOPEDICS, LLC, ("BMO"), BIOMET U.S. RECONSTRUCTION, LLC ("BMR"), and BIOMET MANUFACTURING, INC., ("BMM"), alleges and states as follows:

INTRODUCTION, PARTIES, VENUE AND JURISDICTION

1. This is a lawsuit over defective hip implant components designed and manufactured by Defendants BMI, BMO, BMR and BMM (hereafter collectively "BIOMET" or "Defendants") and distributed within Maryland by Defendants SHOOP and BMA (hereafter collectively "DISTRIBUTORS").

2. The particular components at issue in this case were marketed by Defendants as the "M2a Magnum Metal-on-Metal" hip system (hereafter "M2a Magnum", "Magnum System"

or "Magnum").

3. Defendants marketed, promoted, and sold the M2a Magnum Hip system that is the subject of this lawsuit.

4. At all times relevant to this Complaint, Plaintiff ANNA LAUGHLIN ("Plaintiff") was and is a resident of Lusby, Calvert County, Maryland.

5. At all times relevant to this Complaint, Defendant MAM was and is a Maryland corporation with its principal place of business at 9114 Philadelphia Road, Suite 100, Baltimore, Maryland and as such is a citizen of the State of Maryland.

6. Defendant SHOOP is Owner/President of MAM and is a citizen of the State of Maryland.

7. At all times relevant to this Complaint, Defendant BMI was and is an Indiana corporation, with its principal place of business in Warsaw, Indiana.

8. At all times relevant to this Complaint, Defendant BMO is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant BMI.

9. At all times relevant to this Complaint, Defendant, BMR, is, and at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant BMI.

10. At all times relevant to this Complaint, Defendant, BMM, is an at all times relevant to this Complaint was, a wholly owned subsidiary of Defendant BMI.

11. Upon information and belief, at all times relevant to this Complaint, DISTRIBUTORS, individually working as independent contractor sales agents and distributors for BIOMET, marketed, sold, supplied and distributed BIOMET's products in Calvert County, Maryland.

12. Upon information and belief, DISTRIBUTORS' relationship with BIOMET is defined in a confidential distributorship agreement between SHOOP and/or MAM and BIOMET.

13. DISTRIBUTORS are and/or employ independent contractors who complete sales calls on surgeons wishing to acquire hip replacement components manufactured by BIOMET for implantation in patients.

14. DISTRIBUTORS marketed, sold, supplied and/or distributed, within Calvert County, the BIOMET products at issue in this Complaint.

15. Upon information and belief, at all times relevant to this Complaint, DISTRIBUTORS received commissions and intended to financially profit from marketing, selling, supplying and distributing BIOMET's products in Calvert County, Maryland.

16. Upon information and belief, DISTRIBUTORS did, in fact, receive payment from BIOMET in relation to the sale of the hip replacement components sold to and implanted in Plaintiff.

17. Within the state of Maryland, DISTRIBUTORS are in the chain of distribution for BIOMET products.

18. As a result of their roles in the chain of distribution of the products at issue in this product liability Complaint, DISTRIBUTORS are contemplated by Maryland Courts as proper defendants in product liability claims involving products they market, sell, supply or distribute.[1]

19. Jurisdiction is proper in Maryland State Courts because Plaintiff and all Defendants lack complete diversity.

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[1] *See Kelley v. R.G. Industries, Inc.*, 304 Md. 124, 157-58 (Md. 1985)(In a strict liability cause of action, "liability may be imposed against a manufacturer or anyone else in the marketing chain, including the retailer.")

20. Venue is proper in Calvert County in that at present and at all times relevant to this action, the actions underlying this suit took place in Calvert County:

a) Defendants do business in this county;

b) Defendants sold Plaintiff's components in this county;

c) Plaintiff was implanted with Defendants' defective products in this county;

d) Plaintiff resides in this county;

e) Plaintiff was and is injured in this county;

f) Plaintiff is being treated for her injuries in this county.

TOTAL HIP ARTHROPLASTY

21. Total Hip Arthroplasty (hereafter "THA") is the term used to describe surgery wherein a patient's natural hip anatomy is replaced with synthetic components. THA is also commonly referred to as "hip replacement surgery." A patient may need a THA for a variety of medical reasons including degenerative bone disease and avascular necrosis.

22. THA involves invasive and traumatic surgery in which a surgeon saws and removes a considerable portion of bone, including the ball, from the top of the femur. In place of the removed bone, the surgeon places a metal shaft, called a "stem," down into what remains of the femoral bone. The portion of the stem which is housed inside the femur may be affixed to the bone via use of bone cement or by a porous coating on the synthetic surface of the stem into which the natural bone will grow. The top of the synthetic metal stem, referred to as the "neck," is not housed inside the femur and remains completely exposed inside the body. A component called a "taper," which can be roughly described as similar to a metal sleeve, fits on top of, and around, the exposed neck of the stem. A synthetic ball, whether made of metal, plastic, or ceramic, is then attached on top of, and around, the taper.

23. The surgeon also replaces the anatomical hip socket, the acetabulum, with an artificial "cup" against which the new, synthetic ball articulates. This cup is sometimes referred to as an "acetabular cup." To implant an acetabular cup, the surgeon removes bone from the natural acetabulum in an effort to create a new hip socket large enough to house the synthetic cup. The surgeon then places the synthetic cup into the newly formed hip socket. The cup affixes to the bone either through the use of screws, bone cement, a porous metal coating on the back of the synthetic cup into which the natural bone will grow, or by a combination of the three.

24. A successful THA results in a hip prosthesis that should last 20+ years in a patient.

25. If a hip prosthesis fails in a patient, the patient's surgeon may recommend a "revision" THA procedure in order to replace the failed hip components.

26. A revision THA is extremely traumatic to a patient, multitudes more so than a primary THA. The surgery is typically much longer, with greater blood loss, greater surgeon difficulty, and greater mortality rate. The rehabilitation period for a revision THA can be much longer.

27. In most revision THA procedures, the synthetic components that must be replaced are either the acetabular cup or the femoral ball or both.

28. In a smaller number of revision THA procedures, a surgeon may find it necessary to replace the synthetic femoral stem, as well. This is especially the case where a patient suffers from a fracture of their synthetic stem.

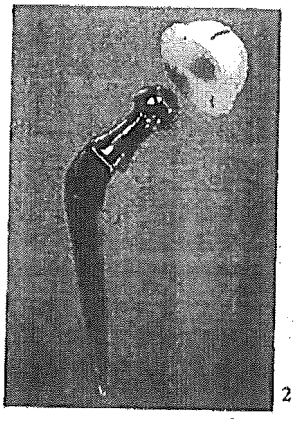
29. The revision of a femoral stem is significantly more physically traumatic to a patient than the revision of an acetabular cup and/or ball. In order to remove the synthetic stem from within the femur, the surgeon must create a large incision down the patient's thigh, then section and remove large sections of the femoral bone in order to get access to the femoral implant.

This process of removing the bone around the implant can be likened to peeling a quartered banana. However, the patient's previously implanted femoral stem has fused with the bone in which it is embedded. This results in an extremely difficult surgery in which the surgeon must carefully separate ingrown bone from the artificial stem. Once the surgeon is able to access, remove, and replace the failed stem, the process of securing new stem in place results in the use of a multitude of screws, clamps, and metal wires in order to replace the sections of removed bone around the new implant. An x-ray of a revised femoral implant can resemble mangled barbed wire surrounding the bone. A patient's recovery from stem revision surgery is prolonged and painful.

30. Further, depending on the mode of failure for a hip prosthesis, the patient's natural anatomy may be so damaged that subsequent revision hip implants will be more likely to fail prematurely.

HIP IMPLANT DESIGN

31. Modern techniques for performing THA and for designing and manufacturing hip replacement components are based on a design introduced by Sir John Charnley in 1962. The design he created and used to perform THA consisted of three components: a one-piece stainless-steel femoral stem and head; an acetabular cup made of Ultra High Molecular Weight Polyethylene (a very hard type of plastic); and acrylic bone cement. A picture is found below for reference:

 [2]

32. Long-term studies of patients undergoing a Charnley THA in the 1960s and early 1970s show excellent results. These studies found that between 85% and 96% of patients still had a well-functioning Charnley hip 25 years after implant. Another study found that 78% of patients still didn't need to have their original Charnley hip replaced even after 35 years.

33. The Charnley hip was not without its weaknesses. The one piece design of the femoral stem and head did not allow surgeons to adjust the implant for any leg-length discrepancies due to surgery. Also, the design of the acetabular cup required the surgeon to apply bone cement to the back of the cup in order to affix it to the natural hip socket. These design elements contributed to a difficult and inflexible surgical procedure for surgeons. Further, the polyethylene plastic used for the cup could wear off as the stainless steel ball articulated inside and against it. As these plastic particles wore off, they damaged local tissue and bone in the patient and could serve to loosen the acetabular cup from the acetabular bone. However, these shortcomings did not occur often, as evidenced by the design's long term survivorship statistics.

[2] Charnley Hip Implant. Available at http://whichorthopaedicimplant.com/wp-content/uploads/2011/06/classic-charnley.jpg. Accessed on Feb. 25, 2014.

34. Over time, varying designs and various compounds of plastic, ceramic, and metal have been implemented for the stem, femoral head (or ball) and the acetabular cup in an effort to improve upon the Charnley design.

35. Briefly, in the 1960s, the orthopedic device industry experimented with various metal-on-metal (hereafter "MoM") designs for hip implants. This design calls for a metal femoral head to articulate directly against the metal interior of an acetabular cup. The perceived benefit of this design was the idea that metal was stronger than plastic and would hopefully last longer and wear less. Further, the strength of the metal would allow for designs that increased range of motion. However, by the mid-1970s, MoM hip implants were completely abandoned in favor of utilizing polyethylene components.

36. Factors that led to the complete abandonment of the MoM designs for hip implants related to:

a. High rates of early revision;

b. The early success of the Charnley prosthesis;

c. Frictional torque between the components;

d. Concerns over the unknown carcinogenic and toxic effects of metal wear;

e. Concerns over metal sensitivity in patients;

f. High rates of infection; and

g. Increased bone strain and fatigue fractures of the bones surrounding the implant.

37. Due to the limited use and subsequent complete abandonment of MoM technology by the mid-1970s, there had been almost no medical or scientific advancement in decades relating to understanding the *actual, clinical* risks associated with using MoM

technology for hip implants.

38. Despite the MoM hiccup in the evolution of THA surgery, various other improvements have been made to the Charnley design in recent decades.

39. Most modern acetabular cups now implement some form of porous coating on the backside where the cup affixes to the hip socket. This allows for bone to naturally grow into the pores so that the surgeon does not need to use screws or bone cement to seat the cup in the bone.

40. Typically, modern acetabular cups are "modular." This means the cups have multiple components. The components of a modular acetabular cup include the cup, which is implanted into the hip socket, and a "liner" which is placed on the inside of the cup and forms the surface against which the femoral head (or ball) articulates.

41. Another improvement was the use of Highly Cross-Linked Ultra High Molecular Weight ("HXUHMW") Polyethylene instead of Charnley's original Ultra High Molecular Weight ("UHMW") Polyethylene. This improved polyethylene is stronger, harder, and reduces the amount of plastic wear produced during articulation of components.

42. HXUHMW Polyethylene Hip Implants were introduced years prior to Defendants' MoM implant.

43. Modern THA implants typically also have a separate femoral stem and femoral head, instead of Charnley's original one-piece design. These two pieces attach at the top of the stem, or "neck." The stem is nearly always made of metal (the particular metal alloy varies depending on manufacturer).

44. The femoral head can be made of HXUHMW Polyethylene or various forms of metal or ceramic.

45. These modern designs have resulted in highly successful implants intended to last and capable of lasting 20+ years in a patient.

THE FDA'S 510(k) CLEARANCE PROCESS

46. In or around 2004, the U.S. Food and Drug Administration (hereafter "FDA") cleared the M2a Magnum System for sale through its 510(k) clearance process.[3]

47. The 510(k) clearance process refers to Section 510(k) of the Medical Device Amendments of 1976 (hereafter "MDA") of the Federal Food, Drug, and Cosmetic Act. Under this process, device manufacturers are only required to notify the FDA at least 90 days before they market a device claimed to be "substantially equivalent" to a device the FDA approved for sale prior to 1976, when the MDA was enacted.

48. No clinical testing is required under this process.

49. Subsequent amendments to the MDA allowed for 510(k) clearance for products deemed "substantially equivalent" to post-MDA, 510(k)-cleared devices.

50. Through this domino effect, devices deemed "substantially equivalent" to devices previously deemed "substantially equivalent" to devices approved for sale by the FDA prior to 1976 could be sold to patients in a matter of 90 days without any clinical testing.

51. BIOMET's 510(k) application claimed the M2a System was substantially equivalent to devices previously cleared through the 510(k) process. Therefore, the M2a System's clearance for sale was based on its purported substantial yet indirect similarity to a medical device approved for sale by the FDA prior to 1976.

52. Clearance for sale under the 510(k) process does not equate to FDA approval of the cleared device.

[3] See "Biomet, Inc. 510(k) Summary of Safety and Effectiveness," attached as **EXHIBIT 1**.

53. In 2012, at the request of the FDA, the National Institute of Health (hereafter "NIH") conducted a thorough review of the 510(k) process, coming to the following major conclusions:

> **The 510(k) clearance process is not intended to evaluate the safety and effectiveness of medical devices with some exceptions. The 510(k) process cannot be transformed into a pre-market evaluation of safety and effectiveness so long as the standard for clearance is substantial equivalence to any previously cleared device.**

54. The NIH explained, "The assessment of substantial equivalence does not require an independent demonstration that the new device provides a 'reasonable assurance of safety and effectiveness.'" Further, the NIH even pointed out that the classification of predicate devices approved for sale prior to the 1976 MDA "did not include any evaluation of the safety and effectiveness of individual medical devices . . . This is common for devices to be cleared through the 510(k) program by being found substantially equivalent to devices that were never individually evaluated for safety and effectiveness, either through the original device classification program or through the 510(k) process."

BIOMET M2A MAGNUM HIP SYSTEM

55. BIOMET designs and manufactures various medical devices and implants.

56. BIOMET marketed itself as "a leader in the design and manufacture of total joint replacement products."[4]

57. Despite the early failure of metal-on-metal technology, and despite the near complete lack of a *clinical* safety record due to the previous abandonment of the technology, BIOMET decided to begin marketing metal-on-metal hips again in 1996.

[4] According to www.biomet.com/orthopedics/index.cfm as archived from March 7, 2009.

58. According to BIOMET's marketing, "During the past decade, BIOMET has emerged as a recognized leader in metal-on-metal articulations."

59. In 1996, BIOMET released the M2a-Ringloc. This design allowed for the use of various metal stems with a metal ball articulating inside a *modular* metal cup. The metal cup utilized a dual-layered liner. The inside of the liner had a metallic surface fused to the polyethylene outside surface. This allowed the metal femoral ball to articulate against the metal inner liner while the outer polyethylene ring protected against a phenomenon called "edge loading."

60. Edge loading occurs when a person moves their hip to the extreme angles allowed by their implant. At this position the metallic neck of the stem of their femoral implant makes direct contact with the metallic edge of the acetabular cup. As the components move against each other at this angle, they can create significantly more metal wear.

61. The Ringloc design protected against this phenomenon by encasing the metal liner with polyethylene, ensuring that metal-on-metal wear would not occur during rim loading.

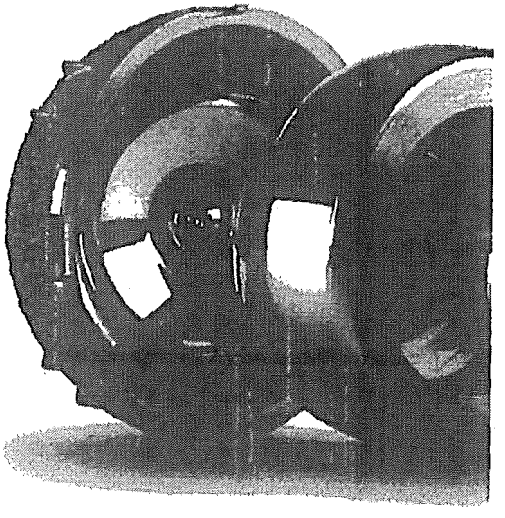
62. In 2001, Biomet began marketing a "monoblock" metal on metal acetabular cup called the M2a-38.

63. A monoblock cup is different from a modular cup in that a monoblock cup does not utilize a liner. Instead, the portion of the cup with porous coating on the outside (which is intended to fuse with the natural bone) and the inside surface of the cup (which articulates against the femoral ball) are part of one, continuous metal component.

64. Utilizing a monoblock design allows for the design of a larger articulating surface inside the cup and a larger femoral ball. The intended end benefit of this design is greater range of motion and stability.

65. However, this design also increases the surface area of metal-on-metal articulation. The increased surface area risks increasing friction between the metal components and increasing wear.

66. In 2004, BIOMET released the M2a-Magnum, a monoblock metal-on-metal hip replacement system. Below is a picture of the Magnum acetabular cup and femoral ball, as found in BIOMET's marketing brochures:



67. BIOMET did not test the Magnum hip system for safety prior to its release. The only testing conducted was "mechanical testing" to "establish substantial equivalence to the predicate devices." No clinical testing was performed whatsoever.[5]

68. The Magnum hip system utilizes a *monoblock* metal cup made of a Cobalt Chromium alloy.

69. The back of the Magnum cup utilizes a porous coating intended to promote bone fixation.

[5] See EXHIBIT 1.

70. The Magnum hip system also utilizes a metallic femoral ball made of a Cobalt Chromium alloy.

71. The femoral ball of the Magnum attaches to the neck of whatever stem is mated with it via a taper made of Titanium.

72. BIOMET markets its Magnum as having the lowest cobalt ion levels of four Metal-on-Metal implant designs.

73. In various marketing materials, BIOMET markets its Magnum as having three-year survivorship rates of "over 98%" and "99.2%."

74. BIOMET states that the Magnum hip system "delivers a clinically proven, unique design that has shown a statistically significant lower revision rate than other MoM implants."

PROBLEMS WITH THE BIOMET M2A MAGNUM HIP SYSTEM

75. Metal wear due to articulation of metal on metal hip implant components is of a particularly small, "microparticle" or "ion" size relative to wear due to articulation of other types of hip implant components, such as Metal on Plastic, Metal on Ceramic, and others.

76. Metal wear microparticles and ions pose a greater danger to local, regional, and systemic body parts because of their smaller size.

77. The destructive effect may also serve to loosen the acetabular cup. A loose acetabular cup, in turn, causes greater amounts of metal wear.

78. Further, research suggests that metal wear can cause neurological problems and carcinogenic cell activity regionally and systemically.

79. The degenerative effects on the patient's anatomy may be so great as to decrease the chances of success for any replacement implant necessitated by the failure of the Magnum System.

80. Despite Defendants' claims of the advantages of the Biomet Magnum System, the product is and always was deeply flawed and defective.

81. The testing done on the product prior to launch was woefully inadequate and not representative of real-world, clinical situations.

82. Defendants marketed their Magnum device as safe merely based on a lack of conclusive clinical connection to cancer and other hazards, as opposed to an affirmative clinical determination of safety.

83. Indeed, Defendants knew that there was no *clinical* evidence to support the contention that its device was safe or effective.

84. Upon information and belief, prior to Plaintiff's implant and revision surgeries, Defendants were aware of defects and unreasonably high rates of problems with the Magnum, including, but not limited to high levels of metal wear causing local and/or systemic damage in patients' bodies.

85. Specifically, Defendants were aware of unreasonably high rates of loosening of the acetabular component, metallosis, pseudotumors, pain, elevated metal levels, and other maladies requiring revision of the hip implant.

86. Prior to marketing and selling the Magnum, Defendants knew or should have known that the Magnum System was not a clinically safe prosthesis.

87. Despite knowing, or being in a position where they should have known of the unreasonable risks associated with the Magnum System, Defendants began to market and sell the Magnum System.

88. Since its inception, the Magnum System experienced an unreasonably high rate of failures worldwide.

89. During the marketing and sale of the Magnum, Defendants knew or should have known that the system was not a clinically safe prosthesis.

90. After Defendants began marketing and selling the Magnum System, they quickly began receiving a high number of reports and warnings from surgeons and others regarding failed Magnum System components.

91. Defendants were made aware of Magnum failures through direct communications with customer surgeons.

92. Defendants did not take proper action in response to surgeon reports and warnings.

93. Despite knowing, or being in a position where they should have known, of the unreasonable risks associated with the Magnum System, Defendants continued to market and sell the Magnum System.

94. The Magnum System was more dangerous than an ordinary consumer would reasonably expect, and the risks associated with it were more dangerous than the risks associated with other hip replacement devices that were available to treat Plaintiff's condition.

DISTRIBUTORS

95. BIOMET utilized sales representatives, including DISTRIBUTORS, who were responsible for educating Plaintiff's orthopedic surgeon regarding the claimed advantages of the products used, answering any questions Plaintiff's orthopedic surgeon asked regarding the products, assisting Plaintiff's orthopedic surgeon at surgery regarding the products, and selling the products to Plaintiff through her orthopedic surgeon agent.

96. DISTRIBUTORS trained and educated their sales staff regarding the Magnum System, including orthopedic and surgical training, product design rationale, surgical technique tips, training in the use of implanting tools, training in selecting the hip replacement components

to mate with the Magnum System, and training on how to sell to orthopedic surgeons, including training on the advantage of the Magnum System over its competitors.

97. DISTRIBUTORS claim on their website that their "team of wellness professionals are continually trained and educated on the most current medical inovations [sic]."

98. Indeed, images available on DISTRIBUTORS' website appear to show a salesperson being trained how to assist performing surgical procedures using BIOMET products.

99. At all times relevant to this Complaint, Plaintiff's orthopedic surgeon, nurses and hospital staff relied on information and assistance from DISTRIBUTORS and their sales representative agents.

100. Prior to Plaintiff's THA surgery, DISTRIBUTORS provided information to Plaintiff's orthopedic surgeon, including but not limited to, the advantages of the Magnum System compared to its competitors, information regarding the design rationale for the Magnum System, surgical techniques on how to implant the Magnum System, and demonstrations on how to implant the Magnum System and the components that could best be mated with the Magnum System,

including providing a variety of scenarios involving the various instrumentation used in implanting the Magnum System.

101. DISTRIBUTORS' sales representative agents were responsible for answering any questions or concerns Plaintiff's orthopedic surgeon had regarding the Magnum System.

102. The above information was provided to Plaintiff's orthopedic surgeon with the intended purpose of convincing and inducing Plaintiff's orthopedic surgeon to use the Magnum System instead of one of the competing hip replacements.

PLAINTIFF'S IMPLANT AND REVISION

103. Plaintiff experienced a history of pain in her right hip that caused her to be treated by Bryan R. Herron, M.D.

104. Dr. Herron determined Plaintiff needed a THA of the right hip.

105. On May 26, 2010, Dr. Herron performed a THA on Plaintiff's right hip at Calvert Memorial Hospital, in Prince Frederick, Maryland.

106. During this THA, Dr. Herron implanted Plaintiff with a number of Biomet M2a Magnum components:

a. Femoral Stem: Biomet Orthopedics, Inc Modular Taperloc Femoral.

b. Taper: Biomet Orthopedics, Inc. "M2a Magnum Taper Adapter."

c. Femoral Head: Biomet Orthopedics, Inc. "M2a Magnum Modular Head."

d. Acetabular Cup: Biomet Orthopedics, Inc. "M2a Magnum PF Cup."

107. In preparation for the May 26, 2010 surgery, Dr. Herron or someone at his direction contacted Defendants, or an agent and/or employee of Defendants, to notify them of the need for the Magnum hip system components.

108. Defendants, through DISTRIBUTORS, selected and provided the specific Magnum System components manufactured by BIOMET for use in Plaintiff and delivered them to the operating room at Calvert Memorial Hospital for surgery. However, DISTRIBUTORS were more than simply a delivery service.

109. After being implanted with the Magnum System, Plaintiff experienced significant pain in her right hip and sought follow-up treatment.

110. Thereafter, Marc Hungerford, M.D. recommended surgery to replace Plaintiff's failed Magnum System components in Plaintiff's right hip.

111. On April 14, 2014, Plaintiff is scheduled to undergo such surgery by Dr. Hungerford at Mercy Hospital in Baltimore, Maryland.

DAMAGES

112. As a direct and proximate result of the defective design, manufacture, marketing and distribution of the Magnum System and component parts, Plaintiff suffered injuries, including but not limited to significant pain, metal wear, loss of enjoyment of life, and limitation of daily activities. Plaintiff expects to continue suffering such injuries in the future as a result of the Magnum System and component parts.

113. As a direct and proximate result of the failed Magnum System, Plaintiff was caused to incur medical expenses, and expects to incur additional medical expenses in the future.

114. As a direct and proximate result of her failed Magnum System, Plaintiff experienced emotional trauma and distress, and is likely to experience emotional trauma and distress in the future.

115. Upon undergoing the recommended revision of her Magnum hip system, Plaintiff expects to undergo lengthy and protracted rehabilitation preventing her from performing activities of daily living.

116. As a direct and proximate result of the failed Magnum System, Plaintiff has incurred lost wages and expects to incur additional lost wages in the future.

COUNT ONE – NEGLIGENCE – ALL DEFENDANTS

117. Plaintiff re-alleges and incorporates by reference paragraphs 1-116 above as if fully stated herein.

118. Defendants, as the designers (BIOMET only), manufacturers (BIOMET only), promoters, marketers, sellers, suppliers, distributors, and servicers of the Magnum System components, owed a duty to use reasonable care in the design (BIOMET only), manufacture (BIOMET only), promotion, marketing, selling, supplying, distribution, and service of Plaintiff's Magnum System.

119. Further, Defendants owed Plaintiff a duty to provide reasonable complete and accurate information to Plaintiff, her orthopedic surgeon, and the orthopedic community regarding Plaintiff's Magnum System.

120. Defendants, in breach of the duties described above, negligently and carelessly designed (BIOMET only), manufactured (BIOMET only), promoted, marketed, sold, supplied, distributed and serviced the Magnum hip replacement components implanted in Plaintiff.

121. Defendants, in breach of the duties described above, negligently and carelessly failed to provide reasonable complete and accurate information to Plaintiff, her orthopedic surgeon, and the orthopedic community regarding Plaintiff's Magnum System.

122. As a direct and proximate result of Defendants' breaches of duty, Plaintiff needlessly suffered injuries as described specifically in paragraphs 112-116.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages in an amount exceeding $75,000, plus costs.

COUNT TWO – NEGLIGENT FAILURE TO WARN – ALL DEFENDANTS

123. Plaintiff re-alleges and incorporates by reference paragraphs 1-116 above as if fully stated herein.

124. Defendants had a duty to give adequate and appropriate warnings to Plaintiff regarding particular risks about the Magnum System that Defendants knew or should have known were involved in Plaintiff's reasonably foreseeable use of the product.

125. Plaintiff's use of the Magnum System was reasonably foreseeable by Defendants.

126. Defendants knew or should have known of particular risks involved in Plaintiff's reasonably foreseeable use of the product.

127. Breaching their duty, Defendants failed to provide adequate or appropriate warnings to Plaintiff.

128. As a direct and proximate result of the conduct of Defendants, Plaintiff needlessly suffered injuries as described specifically in paragraphs 112-116.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages in an amount exceeding $75,000, plus costs.

COUNT THREE – STRICT LIABILITY FAILURE TO WARN – ALL DEFENDANTS

129. Plaintiff re-alleges and incorporates by reference paragraphs 1-116 above as if fully stated herein.

130. At the time that Defendants designed (BIOMET only), manufactured (BIOMET only), promoted, marketed, sold, supplied, distributed and serviced the Magnum hip replacement components implanted in Plaintiff, such components contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

131. The hip replacement components reached Plaintiff without substantial change in the condition in which they were sold.

132. At the time and on the occasions in question, the Magnum hip system components were being properly used for the purpose for which they were intended, and such components were in fact defective, unsafe and unreasonably dangerous.

133. The foreseeable risk of harm from the defects in the Magnum hip system components could have been reduced or avoided by providing adequate instructions or warnings.

134. Defendants failed to provide adequate instructions or warnings regarding the defects in the Magnum System which were known by Defendants or should have been known by Defendants.

135. As a direct and proximate result of the lack of reasonable and adequate instructions or warnings regarding the defects in the Magnum System, Plaintiff suffered injuries as described specifically in paragraphs 112-116.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages in an amount exceeding $75,000, plus costs.

COUNT FOUR – STRICT LIABILITY – ALL DEFENDANTS

136. Plaintiff re-alleges and incorporates by reference paragraphs 1-116 above as if fully stated herein.

137. At the time that Defendants designed (BIOMET only), manufactured (BIOMET only), promoted, marketed, sold, supplied, distributed and serviced the Magnum hip replacement components implanted in Plaintiff, such components contained defects that made them unreasonably dangerous beyond the expectations of the ordinary consumer, and were unfit for their intended use.

138. The hip replacement components reached Plaintiff without substantial change in the condition in which they were sold.

139. At the time and on the occasions in question, the Magnum System components were being properly used for the purpose for which they were intended, and such components were in fact defective, unsafe and unreasonably dangerous.

140. The hip replacement components, for the reasons stated herein, were defective and unreasonably dangerous in design and manufacture.

141. As a direct and proximate result of the defects in the Magnum System, Plaintiff suffered injuries as described specifically in paragraphs 112-116.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages in an amount exceeding $75,000, plus costs.

COUNT FIVE – BREACH OF IMPLIED WARRANTY – BIOMET DEFENDANTS

142. Plaintiff re-alleges and incorporates by reference paragraphs 1-116 above as if fully stated herein.

143. BIOMET impliedly warranted that the Magnum System and its component parts were merchantable and fit for the ordinary and intended purposes for which hip systems are used.

144. Plaintiff was a foreseeable user of the Magnum System.

145. Plaintiff's surgeon, as purchasing agent, purchased the Magnum System for Plaintiff from BIOMET.

146. At all times relevant to this Complaint, Plaintiff was and is in privity with BIOMET.

147. Plaintiff used the product for its ordinary and intended purpose.

148. The Magnum System failed while being used for its ordinary and intended purpose.

149. As a direct and proximate result of BIOMET's breach of implied warranty, Plaintiff suffered injuries as described specifically in paragraphs 112-116.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages in an amount exceeding $75,000, plus costs.

COUNT SIX – BREACH OF EXPRESS WARRANTY – BIOMET DEFENDANTS

150. Plaintiff re-alleges and incorporates by reference paragraphs 1-116 above as if fully stated herein.

151. BIOMET sold and Plaintiff purchased, through her purchasing agent surgeon, the Magnum System.

152. BIOMET expressly warranted by affirmation, promise, description, and sample to Plaintiff and her physician that the Magnum System components were of a quality and character suitable for implantation and extended safe use in Plaintiff.

153. Such representations by BIOMET were meant to induce Plaintiff, through her physician, to purchase the Magnum System components.

154. The Magnum System components did not conform to the representations made by BIOMET in many ways.

155. Within a reasonable time after Plaintiff knew or should have known of the failure of her Magnum hip system components, Plaintiff gave notice to BIOMET of such failure.

156. BIOMET breached the express warranty it provided with the device in violation of § 672.313, Fla. Stat. (2011) as aforesaid.

157. As a direct and proximate result of BIOMET's breach of its express warranty, Plaintiff suffered injuries as described specifically in paragraphs 112-116.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages in an amount exceeding $75,000, plus costs.

COUNT SEVEN – VIOLATION OF MARYLAND CONSUMER PROTECTION ACT – ALL DEFENDANTS

158. Plaintiff re-alleges and incorporates by reference paragraphs 1-116 above as if fully stated herein.

159. Defendants used deception, misrepresentation, and omission to convince Plaintiff's orthopedic surgeon, acting as Plaintiff's agent, that the components at issue were safe, effective, and superior to other products readily available for use.

160. Defendants used deception, misrepresentation, and omission to convince Plaintiff's orthopedic surgeon, acting as Plaintiff's agent, to purchase the components at issue on behalf of Plaintiff and implant them in Plaintiff.

161. As a result, Plaintiff purchased the product for personal use.

162. As a direct and proximate result of Defendants deceptive acts and omissions, Plaintiff suffered injuries as described specifically in paragraphs 112-116.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages in an amount exceeding $75,000, plus costs.

COUNT EIGHT – MISREPRESENTATION – ALL DEFENDANTS

163. Plaintiff re-alleges and incorporates by reference paragraphs 1-116 above as if fully stated herein.

164. Defendants made representations in the course of their business and/or during the transaction in which the product at issue was sold, including representations to Plaintiffs' orthopedic surgeons, in which Defendants stated that the components at issue in this lawsuit for safe and effective for use as a hip replacement system. Indeed, Defendants made representations stating that the components at issue here were safer and/or more effective than other metal-on-metal and non metal-on-metal hip systems which were available for implantation in Plaintiff.

165. Defendants failed to disclose important information concerning the safety and efficacy of the components at issue, such as unreasonable rates of product failures and surgeon warnings.

166. The above referenced representations and/or omissions were false and/or were made without knowledge of their truth or falsity.

167. Defendants did not exercise reasonable care in communicating the information to Plaintiff and/or Plaintiff's orthopedic surgeon.

168. Plaintiff and/or Plaintiff's orthopedic surgeon justifiably relied on the representations and/or omissions made by Defendants, as set forth herein.

169. As a direct and proximate result Plaintiff suffered injuries as described specifically in paragraphs 112-116.

WHEREFORE, Plaintiff respectfully demands judgment against Defendants for compensatory damages in an amount exceeding $75,000, plus costs.

Dated this 9th day of April, 2014.

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ATTORNEYS FOR PLAINTIFF

JURY DEMAND

Plaintiff demands trial by jury on all issues.

Christopher H. Mitchell

CERTIFICATE PURSUANT TO RULE 1-313

I, undersigned counsel for the plaintiff, hereby certify that I am a member in good standing of the Bar of the State of Maryland.

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BIOMET INC

510(k) Summary of Safety and Effectiveness

Applicant/Sponsor:	Biomet Manufacturing Corp.
Contact Person:	Kacy Arnold Regulatory Specialist
Proprietary Name:	M²a™ Magnum™ System
Common Name:	Metallic Acetabular Articulation
Classification Name:	Hip joint metal/metal semi-constrained, with uncemented acetabular component prosthesis (888.3330)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
The M²a™ Magnum™ System is substantially equivalent to:

- K011110 M2a™ Acetabular System 38mm *(Biomet)*
- K984028 Bio-Moore Endo Heads *(Biomet)*
- K002106 New Bio-Moore Endo Head, Taper Adapter *(Biomet)*
- K031963 Conserve® Plus Spiked Shell and Conserve® Total 56mm Femoral Head *(Wright Medical)*
- K021249 Metal Transcend® Articulation System (Wright Medical)

Device Description:

Summary of Technologies: The M²a™ Magnum™ Hip System technological characteristics (material and design) are similar to predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

All trademarks are property of Biomet, Inc.